FOR ARGUMENT

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1978

No. 78-605

UNITED STATES OF AMERICA, *et al.*,

Petitioners,

v.

GLEN L. RUTHERFORD, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF *AMICUS CURIAE* OF THE "SAVE THE UNITED STATES MOVEMENT, IMPROVING PUBLIC HEALTH AND PHYSICAL FITNESS OF THE UNITED STATES CITIZENS"

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OPINIONS BELOW

The opinion of the Court of Appeals (Pet. App. 1a-7a) is reported at 582 F.2d 1234. The opinion of the District Court (Pet. App. 11a-44a) is reported at 438 F. Supp. 1287. The decision of the Commissioner of Food and Drugs (Pet. App. 45a-274a) is reported at 42 Fed. Reg.

39768. The opinion of the District Court rendered after the first hearing, dated Oct. 10, 1975 (hereinafter referred to as the District Court's first opinion), is reported at 399 F. Supp. 1208. The opinion of the Court of Appeals rendered on Oct. 12, 1976, upon appeal from the District Court's first opinion (hereinafter referred to as the Circuit Court's first opinion), is reported at 542 F.2d 1137.

INTEREST OF AMICUS CURIAE

The "Save the United States Movement, Improving Public Health and Physical Fitness of the United States Citizens" is an unincorporated, nonprofit organization, founded by Robert Collins Hoffman (popularly known as "Bob Hoffman") of York, Pennsylvania. Mr. Hoffman is the organization's national chairman, its promoter, and its guiding light. Ms. Gertrude Engel of Washington, D.C. is its executive director. The interest of this organization in the present action is predicated entirely on considerations of patriotism, public-spiritedness, and a profound conviction that Americans will be healthier, and stronger if they discipline themselves to follow proper health practices, and if they are freed from unnecessary government intervention in their choice of health regimes. *Amicus* has no commercial interest in Laetrile. All parties to this appeal have filed written consent for the filing of this *amicus curiae* brief.

QUESTIONS PRESENTED BY AMICUS

1. Does the Food and Drug Administration's (FDA's) denial of access to Laetrile by banning it from importation and transportation in interstate commerce constitute an unconstitutional invasion of the intended user's (patient's) right of privacy where:

   a) The patient is an informed, adult, consenting, terminal cancer victim;
   b) The patient is acting under the recommendation and care of a licensed physician; and
   c) The Laetrile is to be used solely by the patient, and not otherwise sold or promoted?

2. Is Laetrile entitled to a "grandfather" exemption from the new drug status provisions of section 201 (p)(1) of the Food, Drug, and Cosmetic Act, as amended (the Act), 21 U.S.C. 321(p)(1), by virtue of the provisions of section 107(c)(4) of P.L. 87-781? [1]
3. In determining Laetrile's possible "new drug" status, or exemption therefrom, pursuant to the statutory provisions referred to in paragraph 2, above, insofar as that determination may affect the right of an informed, consenting, adult, terminal, cancer patient to have access to such Laetrile for his own consumption, is the FDA, in applying the tests of "safety" and "efficacy" as required by the said statutory provisions, also required to establish reasonable standards adapted to the unusual circumstances of the case, by which the terms "safety" and "efficacy" can be measured?

STATEMENT OF THE CASE

This class action (under Rule 23, Federal Rules of Civil Procedure) was initiated by plaintiffs Jimmie Stowe and Gene Sneider, terminally ill cancer victims, on their individual behalf, and that of a class composed of other

[1] This is one of the so-called "transitional provisions" of the 1962 amendment to the Act, reported in the note following 21 U.S.C. 321.

terminally ill cancer victims and their spouses. In anticipation of the demise of both plaintiffs, which demise did in fact occur, the present plaintiff, Glen L. Rutherford, also a terminally ill cancer victim, intervened, and is now identified as plaintiff-respondent in the case now before this Court.

The relief prayed for was an order directing the United States of America, and the Secretary of Health, Education and Welfare to desist from prohibiting the importation and transportation in interstate commerce of that drug known as Laetrile (also referred to as Amygdalin, or vitamin B-17), which order was needed to make possible the preservation of plaintiff's life.

In the first trial of the case on its merits before the United States District Court, W.D., Oklahoma, Judge Bohanon found, on p. 1210, that the plaintiff had been diagnosed, in 1971, as showing an invasive adenocarcenoma, as evidenced by a large prolapsing polyp in the lower colon. Plaintiff's regular physician had strongly recommended an immediate operation, which might involve the removal of plaintiff's rectum. At that stage, plaintiff was considered to be terminally ill. Plaintiff elected to refuse such an operation, and, instead, went to Mexico, where he submitted to a series of Laetrile treatments, administered by a competent physician. As a result thereof, the polyp disappeared completely, without operation, and plaintiff was able to return to his normal work. [2] Plaintiff was advised, however, by his Mexican physician, that he should continue to take Laetrile, as prescribed, in order to prevent a recurrence of his cancer. This he proceeded to do.

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[2] Fortunately, plaintiff is still alive, and well.

In 1975, however, his shipment of Laetrile imported from Mexico, was confiscated by the FDA while still in the hands of the carrier. The latter was jailed, and threatened with a $10,000 fine. This course of events resulted from the legal processes previously set into motion by the FDA for the purpose of preventing any importation of Laetrile, or trafficking in interstate commerce therein. As a result of said FDA action, plaintiff was deprived of all means of procuring his Laetrile, and felt that he was in danger of dying.

The District Court on October 10, 1975, thereupon granted a preliminary injunction restraining the FDA from prohibiting the further importation of Laetrile destined for the plaintiff, or others in his class.

On appeal to the Tenth Circuit Court of Appeals, (see First Circuit Court opinion) the latter upheld the District Court's temporary injunction, but remanded the case in order that the FDA might hold further hearings, and build a record on the question of Laetrile's new drug status and eligibility for a grandfather exemption.

Such further hearings were, in fact, held by the FDA, which resulted in a reaffirmation of the FDA's original position, and a reissuance of its order prohibiting the importation of Laetrile, and the trafficking therein, in interstate commerce.

Back to the aforesaid District Court for a second trial on the merits, Judge Bohanon again ruled for the plaintiff, and issued a permanent injunction against the FDA forbidding them from interfering with the importation of Laetrile destined for the plaintiff or others in his class, or the trafficking in interstate commerce therein. On the second appeal to the aforesaid Tenth Circuit

Court of Appeals the latter affirmed the decision of the District Court, but on grounds different from those upon which Judge Bohanon had predicated his decision. The case now comes on before the United States Supreme Court, upon a writ of *certiorari*, granted by this Court on January 27, 1979.

DECISIONS OF THE LOWER COURTS

The District Court found, on p. 1211 of the first District Court opinion, that the plaintiff had been cured of his cancer by the use of Laetrile, that he would have to continue to use it to prevent a recurrence, and that Laetrile was non-lethal, and safe. The Court also found that a new drug application previously had been filed with the FDA on behalf of Laetrile, pursuant to the provisions of section 505(b) of the Act, 21 U.S.C. 355 (b), but that the FDA had not acted on said application either affirmatively, or negatively, within the 180 days allowed by section 505(c) of the Act, 21 U.S.C. 355(c). The Court concluded, therefore, that it (the Court) had jurisdiction to review the matter, since the provisions of section 505(h) of the Act, 21 U.S.C. 355(h) providing for direct appeal to the Circuit Court of Appeals from an adverse FDA ruling on an application for approval of a new drug application were only applicable where the FDA actually took action on the application (either affirmative or negative). Where the FDA merely delayed, through its own inaction, plaintiff was entitled to appeal to the District Court, pursuant to 5 U.S.C. 704 and 706. The Court also concluded that the FDA had the affirmative duty to render a judgment on the new drug application.

On appeal, the Circuit Court of Appeals (in the Circuit Court's first opinion) ruled that the District Court had erroneously held that the FDA was required to make a decision (either affirmative or negative) on a request for approval of a new drug application, if, as was the case here, the application was defective. The FDA has no affirmative duty to conduct such research as would be necessary to correct the defects of the application, and has no duty to act on the application, in the presence of such defects. FDA's responsibility to approve or disapprove the new drug application can only ripen if the application is in proper form. The reason for this is that Congress contemplated that the applicant, and not the FDA, should carry the burden of putting the application into proper form, which entails a long, tedious, and expensive procedure.

However, the Court also held that the determination of whether Laetrile was a new drug, pursuant to section 201(p)(1) of the Act, 21 U.S.C. 321 (p)(1), was to be made by the FDA only as a result of a hearing and a fair and equitable evaluation of the evidence, all of which should be made a matter of record, reviewable by a District Court pursuant to 5 U.S.C. 704 and 706. Such hearing would involve, not only the question whether the drug in question was generally regarded as safe, but whether it qualified for one of the two grandfather exemptions provided by the Act. The case was remanded to give the FDA an opportunity to conduct such hearing.

When the case came before the District Court for the second time, Judge Bohanon decided, first, that Laetrile was not a new drug, by virtue of the grandfather exemption of section 107(c)(4) of P.L. 87-781. Specifically, he found that on the day prior to the enactment of the 1962 amendment to the Act, Laetrile was not a "new

drug," i.e., it was generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as being safe for use under the conditions prescribed. He decided, second, that depriving the plaintiff of the right to obtain Laetrile, under the circumstances of the case, constituted an interference with plaintiff's constitutional right of personal privacy, as guaranteed to him by the First, Fourth, Ninth, and Fourteenth Amendments to the United States Constitution. The injunction against the FDA was thereupon made final.

The Circuit Court of Appeals sustained the results of Judge Bohanon's decision, but predicated its judgment on entirely different grounds. It specifically sidestepped the grandfather and the constitutionality issues. It predicated its decision, rather, on the ground that the tests of "safety" and "efficacy" required by section 201(p)(1) of the Act, 21 U.S.C. 321(p)(1), in determining whether a proposed drug was a "new drug", had no application whatsoever to drugs requested by an informed, consenting, terminally-ill cancer patient, in the absence of special standards by which these terms could rationally be measured. The Court continued the permanent injunction previously issued by the District Court, but limited its application to terminal patients ingesting Laetrile only intravenously, through the ministrations of a licensed physician, and upon his recommendation.

EXPLANATORY BACKGROUND MATERIAL ON THE LAETRILE CONTROVERSY

The legal controversy over Laetrile falls outside the mainstream of ordinary litigation. Its precedents are few, and its implications profound. It transcends mere questions of methodology, and furnishes, rather, a forum where two mighty opposing philosophies of medicine

have chosen to join issue. Quite expectedly, the essential facts have become obscured behind a veil of misinformation, not always unwittingly fabricated. The following explanation of the nature of Laetrile and of its relationship to the entire cancer problem serves only to enable the Court better to understand the reasonableness of the Laetrilist position, the nature of the present controversy, and both the subtlety and significance of the latter's dimensions.

Regarding the pervasiveness of the cancer affliction, Judge Bohanon, in ftn. 27 of p. 1300 of his opinion, said the following:

> *1977 Cancer Facts and Figures* by the American Cancer Society estimates that 1977 will have produced an estimated 690,000 new cancer cases; and that over 54 million Americans now living will eventually have cancer, which is one out of every four Americans living. The pamphlet also states that over the years cancer will strike in approximately two of every three families, that in the 1970's there will be an estimated 3.5 million cancer deaths, 6.5 million new cancer cases, and more than 10 million people under medical care for cancer. Only about 1/3 of all people who get cancer this year will be alive five years after treatment, according to the publication.

Regarding the prominence of the role which Laetrile is currently playing, Charles G. Moertel, M.D. of the Mayo Clinic, Rochester, Minnesota, recently made the following public statement:

> Today in the United States Laetrile has become one of the most commonly employed chemotherapeutic agents for the treatment of cancer. It has been estimated that during 1977 over 50,000 cancer patients in America consumed over 1,000,000 grams of Laetrile per month. From the standpoint of magnitude alone, Laetrile has become a public health issue of

> major significance . . . . The Laetrile issue . . . has clearly gone far beyond the point of just another quack medicine . . . .

One man who is as well-qualified as any other in the United States to speak authoritatively on the specific subject of cancer research, is the distinguished biochemist Dean Burk, Ph.D., president of the Dean Burk Foundation, who for 35 years was associated as chemist with the National Cancer Institute, National Institutes of Health. As its chief chemist for 16 years, and head of its Cytochemistry Section, he was able to acquire significant insights into the problem of cancer detection and control, which entitle his statements to unusual credibility. His list of publications, memberships, and recognitions is long, and imposing.

For purposes of inclusion in this *amicus curiae* brief, Dr. Burk made the following statement:

> Vitamins are organic chemical compounds required by a living organism in calorically negligible amounts for optimal metabolic life functions, and must be supplied in the given organism's diet or nutrition as derived from production by some other organism or by chemical synthesis by man.
>
> Amygdalin[1] is a member of the vitamin B complex (B-17) and thus by definition nontoxic, highly water-soluble, remarkably ubiquitous, and crystallizable. It was first isolated and named in 1830, first

[1] Judge Bohannon, in his decision, in footnote 17 on page 1295, said: "Numerous judicial determinations have been made equating Laetrile and Amygdalin . . . The administrative record clearly establishes that Laetrile and Amygdalin are equivalent, and have been recognized as such for over 20 years.

used to treat cancer in 1843, and first recognized as a vitamin in 1970 by E.T. Krebs, Jr. In animals it has been shown in many laboratories of the world to inhibit cancer growth rates, and cancer spread to other parts of the body (metastases), [and has been instrumental in the] lengthening of life span, or improved health and appearance, as reported extensively in Congressional hearings and scores of scientific articles (any and all statements to the contrary notwithstanding). It has been found to act similarly in a statistically significant fraction of thousands of humans under care of physicians throughout the world, and is currently consumed in the daily diet of upwards of one hundred thousand Americans, as taken either by mouth or injection. Laetrile is consumed by more Americans ill or threatened with cancer than any other single, recognized, chemotherapeutic anticancer agent, with the possible exception of ascorbic acid (vitamin C), ... Like all vitamins, vitamins B-17 and C act only under appropriate conditions of their respective dietary deficiencies that give rise to corresponding deficiency diseases, lesions, or symptoms, and their actions may be curtailed or eliminated when other vitamins or food substances are also sufficiently limiting. . . .

Amygdalin has been widely recognized for over one hundred years as nontoxic for man, even at dosages much greater than, in the language of the Act, those which do "not ordinarily render it injurious to health." Conventional dosages taken by untold numbers of Americans range from one to twenty grams daily, without notable toxicity or pharmacologic injury. . . . For over one hundred years standard pharmacology and toxicology compendia have indicated that amygdalin is nontoxic by standards accepted as nontoxic. . . .

The relevant literature discloses an unbridgeable gap between the basic thinking of Laetrilists and anti-Laetrilists. The high tension generated by the resultant controversy is explainable, not alone by the fact that countless cancer victims consider their right to Laetrile a matter of life or death, literally, but that those tens of thousands of professional reputations, and staggering investments of time and money presently committed to establishing the anti-Laetrilist point of view would be, if that point of view were successfully challenged, seriously undermined, and the comfortable respectability of current medical practices reduced to shambles.

The logic behind current medical opposition to Laetrile was explained by Ms. Gertrude Engel, executive director of the organization in whose behalf this *amicus curiae* brief is filed, and who has had many year's experience in the promotion of sound nutrition and related sound health practices. In a recent statement, Ms. Engel, who is also a columnist, said:

> The opposition of medical orthodoxy to Laetrile is at least understandable, if not justifiable. Because doctors, generally, have had no experience with Laetrile, they fear it. It is new. It is different. It seems like an absurd oversimplification. If apricot pits can do more against cancer than five billion dollars worth of radiation equipment, and the whole frightening panoply of anti-cancer weapons, then where do the doctors and technicians, the medical colleges and professors, and the learned medical journals go from here? Moreover, there is always the specter of malpractice suits. As long as a physician follows the well-beaten path of consensus therapy, he knows he is solidly safe against the assaults of irrationally-emotional cancer victims. But once,

> when the going is tough, the support of his colleagues is withdrawn, what kind of legal pitfalls lie ahead? The risks are frightening, which only the most robust of practitioners are willing to take.

Dr. Ernest T. Krebs, Jr., biochemist in San Francisco (who is considered the father of Laetrile), propounded the theory, in 1952, that:

> cancer, like scurvy, and pellagra, is not caused by some kind of mysterious bacterium, virus, or toxin, but is merely a deficiency disease aggravated by the lack of an essential food compound in modern man's diet. He identified this compound as part of the nitriloside family which occurs abundantly in nature in over twelve hundred edible plants. . . . It is particularly prevalent in the seeds of those fruits in the *prunus rosacea* family (bitter almond, apricot, blackthorn, cherry, nectarine, peach, and plum), but also is contained in grasses, maize, sorghum, millet, cassava, linseed, apple seeds and many other foods that, generally have been deleted from the menus of modern civilization. [3]

Informed Laetrilists, who generally accept the above thesis of Dr. Krebs, approach the cancer problem, not with the objective of trying to find some miracle treatment that can destroy, by excising, burning, or poisoning the visible manifestations of cancer (polyps, tumors, lesions, etc.), but to find and remove the *underlying causes*, or *conditions*, of cancer, which, according to them, are associated with a metabolic deficiency.

Laetrilists fault medical orthodoxy for failing to distinguish between:

a) Cancer symptoms;

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[3] Quoted from: "World Without Cancer", by G. Edward Griffin (1977 reprinting), pp. 51, 52.

b) Immediate causes of cancer, or "triggering agencies" such as tobacco smoke or carcinogen-impregnated air, or unnatural stresses, and physical or chemical irritants; and,
c) The underlying cause, or condition, of cancer, which is a metabolic deficiency.

If the underlying cause is identified and removed, it is reasoned, the symptoms and triggering mechanisms become of secondary importance. Moreover, from a pragmatic point of view, it makes more sense to concern ourselves with the basic cause or condition of cancer, since, according to Laetrilist orthodoxy, that cause is associated with a single, relatively easily-understood concept, whereas the mechanisms which trigger off the manifestations or symptoms of cancer are almost infinite in number, and, by very definition, can never be completely understood, or, *a fortiori*, removed.

The Laetrile erudites generally consider cancer cells to be similar, if not identical, to trophoblast cells which, during pregnancy, manufacture the tissues forming the umbilical cord and placenta, but which, after their task is done, cease all further proliferation because of the action of certain growth-arresting enzymes which the body manufactures for that purpose. When, due to a nutritional deficiency or other causes, this natural defense does not function adequately, the body becomes vulnerable to the uncontrolled proliferation of cancer cells.

The remedy, according to Laetrilists, is to restore the patient's proper natural metabolic balance through administering large doses of that deficient nutritional element needed to enable the body to combat the cancer. This approach is reminiscent of the epoch when scurvy

was first found to result from a vitamin C deficiency. The remedy: heavier doses of vitamin C.

The above explanation, of course, is an oversimplification of both the problem and the solution. The complications are many. One of them is the fact that after cancer cells have extensively proliferated into vital areas of the body, and after the patient has subjected himself to injurious surgery, radiation, and/or chemotherapy, the probabilities are that serious damage will have been caused to vital organs, and to the body's natural defense mechanism. Even the most effective cancer remedy cannot render whole an organ which has been irreparably damaged either by cancer, or by destructive cancer treatments.

The Laetrilists take the position that too many resources (which total millions of hours in time, and billions of dollars in wealth) have been spent in a futile search for ways of reducing cancer symptoms, and not enough in finding out what cancer really is. As a result, the bottom-line statistic on cancer recovery, after treatment, is appallingly bad, and has scarcely improved in a hundred years.

As stated by John A. Richardson, M.D., who has had long experience with the administration of Laetrile (but who, incidentally, was barred from practicing medicine in California for that reason):

> No longer were we treating the lump or bump; we were treating the entire patient. While the medical profession continued to think of cancer as a *tumor*, we recognized it as a systemic *condition*. A lump, or bump is merely the symptom, not the disease itself. No wonder we doctors had failed to control cancer

all these years. We had been attacking the symptom and ignoring the disease.[4]

Glen D. Kittler, summarized the difference between the two approaches in the following words:

> Scientifically, there has always been a canyon between the Laetrilists and the anti-Laetrilists. The anti-Laetrilists, sometimes called the Cancer Establishment, have maintained that cancer is a multiplicity of diseases—perhaps hundreds—which all exhibit themselves in one way—cancer. The Laetrilists, on the other hand, have maintained that cancer is a single disease with a multiplicity of exhibitions. From the point of view of the Establishment, then, it would seem highly unlikely that medical science will ever overcome cancer. The Laetrilists, however, at least provide a starting point and a direction to go.[5]

The following general propositions regarding Laetrile must be made at this juncture:

1. Informed Laetrilists do not all agree on the precise rationale to explain the effectiveness of Laetrile therapy. They are in total agreement, however, that we stand only on the threshold of understanding the vital forces at work in making Laetrile effective. Much work yet needs to be done to unlock the mysteries of this promising cancer treatment.
2. Laetrilists are modest in their claims for Laetrile's effectiveness. They are unanimous, however, in their insistence that the percentage of

[4] "Laetrile Case Histories", p. 11 by John A. Richardson, M.D. and Patricia Griffin, RN. (1977 edition).

[5] "Laetrile, Nutritional Control for Cancer with Vitamin B-17", by Glenn D. Kittler, revised edition, 1978, page 9.

Laetrile patients whose cancer has been "controlled" (as opposed to "cured") is significantly higher than that of patients treated with orthodox remedies, under comparable conditions.

3. Laetrilists point out, however, that entirely apart from the percentage of cancer patients whose cancer has become "controlled" through the effects of Laetrile, there are literally hundreds of thousands who have received other types of very tangible benefits, such as relief from pain and distress and loss of weight. More important, they have been spared the brutual, humiliating, and degrading therapy which is sometimes required by traditional methods, involving the loss of genitals, breasts, rectum, etc. Measured by these immediate benefits, alone, it is argued, Laetrile has justified itself.
4. Laetrilists agree with anti-Laetrilists that early diagnosis and treatment of cancer is requisite for maximizing the chances of recovery. Delay in receiving treatment may result in destruction of whatever opportunity there is for controlling the cancer (although the cancer patients whose illness had been declared "terminal" by orthodox medicine, and whose cancer has subsequently been brought completely under control through the use of Laetrile, number in the many thousands.)
5. Laetrilists agree that Laetrile should be administered only to cancer patients, (but certainly should not be limited to terminal patients) upon recommendation, and under the care, of a competent physician, after giving informed consent. *Under no circumstances* should Laetrile become an over-the-counter drug.

6. As more light is shed on the subject, the view of most Laetrilists will be confirmed that Laetrile will only be minimally effective unless administered in connection with:

   a) A strict dietary regime which stresses the importance of foods which do not place an unnecessary digestive load on the pancreas;
   b) The ingestion of extra vitamins (in addition to B-17), and enzymes.

It follows that the beneficial results of Laetrile will depend in large measure on the intelligence of the patient, and his or her willingness to follow rigid dietary strictures.

Admitting as they do that there is still much to learn about Laetrile and its supporting rationale, Laetrilists contend that in view of the fact that:

a) Laetrile has been endorsed by many of the world's most informed men in the field of cancer (as will be pointed out further in this brief);
b) Research in the area of Laetrile therapy has shown it to be more fruitful of results than conventional therapy, both in controlling cancer, and in bringing relief from pain and avoiding the necessity of enduring expensive, excruciating, and degrading conventional treatments;
c) Laetrile stands up well against the government-sanctioned alternatives; and
d) Laetrile has reached and passed the threshold of rationality as an alternative to orthodox therapy;

the law should not make criminal that commerce in Laetrile destined for those who desire it for their own use. The lowly apricot pit, and its derivatives and cog-

nates, may turn out to be the most generous medical benefactor yet discovered by man.

This background discussion on Laetrile is concluded with a quotation of Stewart M. Jones, M.D. and Ph. D. (Palo Alto, California), an authority in this field, as follows:

> This theory [of Laetrile] is the oldest, strongest, and most plausible theory of cancer now extant. It has stood the test of seventy years of confrontation with new information about cancer without ever being disproved by any new facts. . . . The voluminous heterogeneous science of cancer developed since then is coherent only in the light of this theory.[6]

SUMMARY OF ARGUMENT

In this brief it is assumed, without conceding, that Laetrile is a drug, as well as a food, under the provisions of section 201(g)(1)(B) of the Act, 21 U.S.C. 321 (g)(1)(B), for the reason that within the mind of the general consuming public Laetrile has become associated with an intended use in the diagnosis, cure, mitigation, treatment, or prevention of cancer. It is assumed that plaintiff, and those in whose behalf this action is brought, are informed, consenting, adult, terminal, cancer victims, who have elected to submit themselves to Laetrile treatment, upon a competent physician's recommendation, and under his supervision. It is *not* assumed that the treatment involved is limited to intravenous injection. *Amicus's* first agrument is that, under these circumstances, the making criminal of, or interdiction, or interference in any way by the United States Government, or

[6] "Nutritional Rudiments in Cancer," Stewart M. Jones, M.D., p. 6.

any of its agencies with, the importation or the transportation in interstate commerce of Laetrile destined for the intended user's (patient's) sole use, and not for sale to another or for general promotion, constitutes an unconstitutional invasion of the patient's right of personal privacy guaranteed to him by the provisions of the First, Fourth, Fifth, and Ninth Amendments to the United States Constituion.

This is for the reason that the invasion of one's individual right of privacy, which includes the freedom to choose the health regime applicable to one's own body, must not be violated except in the presence of an overriding substantial and compelling State interest. The alleged overriding substantial and compelling State interest in support of FDA's strictures placed upon the trafficking in Laetrile, namely that of discouraging cancer patients from resorting to unproven cancer remedies which might discourage, to their detriment, their timely recource to state-sanctioned alternatives, is not of sufficient weight to override the patient's right of privacy.

Some of the factors which the Court is entitled to consider in balancing the State's interest in protecting its citizens from inflicting self-injury, against the citizens' right to select their own medical therapy, are the following.

1. Whether the therapy is safe;
2. Whether the therapy is reasonable, and relatively effective vis-a-vis its state-sanctioned alternatives. "Effective" includes not only controlling or curing the disease (cancer), but realizing other benefits, such as: relieving pain, increasing the quality of life, and eliminating the need for other excruciating, and

destructive state-sanctioned remedies which frequently do more harm than good;

3. Whether the patient is an informed, consenting, adult, terminal, cancer patient, receiving his Laetrile on doctor's advice, and under his supervision;
4. Whether there is a rational connection between the alleged paramount State purpose (to discourage a self-destructive recourse to non state-approved alternative remedies) and the means employed to accomplish that purpose (the making criminal and interdiction of trafficking in Laetrile).

It is not argued that all of the above factors must be resolved in favor of the plaintiff in order to support the paramountcy of the right of individual privacy over the State's right to prevent self-inflicted injury (i.e., to proscribe traffic in Laetrile). A favorable resolution of item number one, above, would probably be sufficient in itself. A combination of numbers one and three should be sufficient, without question. A favorable resolution of the other two items makes the case that much stronger.

Since all the above factors can be favorably resolved, in the instant case, in favor of the plaintiff (Laetrile), the case is much stronger than would be minimally necessary to justify a judgment sustaining the position of the federal District Court.

Amicus's second argument is that Laetrile is not a new drug, for the reason (among others) that it is exempt by virtue of the provisions of section 107 of P.L. 87-871, appearing in the note following 21 U.S.C. 321. This is one of the two grounds upon which District Court Judge Bohanon predicated his second opinion.

Amicus's third argument is that when applicable to an informed, consenting, adult terminal cancer patient, the tests of "safety" and "effectiveness" as required by section 201(p)(1) of the Act, 21 U.S.C. 321(p)(1), have no meaning in the absence of special standards applicable to those circumstances.

In the absence of such standards, the tests cannot be rationally applied, and Laetrile cannot be considered a new drug, and its importation proscribed, insofar as the proscription would deprive plaintiff of his Laetrile. *Amicus* contends that terminal cancer patients are as entitled to "safe" drugs as any other patient, but that rational standards are required, before the test can be applied. However in view of the fact that the District Court found from the record that Laetrile was generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as being safe, and thus meeting the requirements of section 201(p)(1) of the Act, 23 U.S.C. 321(p)(1), the consideration of this point, insofar as it relates to safety, is moot.

ARGUMENT

I.

THE MAKING CRIMINAL, OR ENJOINING (1) THE IMPORTATION OF A NEW DRUG, OR (2) THE INTRODUCTION OF A NEW DRUG INTO INSTERSTATE COMMERCE, BY THE UNITED STATES GOVERNMENT, CONSTITUTES AN INVASION OF THE INDIVIDUAL RIGHT OF PRIVACY GUARANTEED TO THE INTENDED USER (PATIENT) BY THE FIRST, FOURTH, FIFTH, OR NINTH AMENDMENTS TO THE CONSTITUTION OF THE UNITED STATES, WHERE THERE ARE NO OVERRIDING SUBSTANTIAL AND COMPELLING STATE INTERESTS REQUIRING IT. WITH REGARD TO THE NEW DRUG LAETRILE, UNDER THE CIRCUMSTANCES OF THE PRESENT CASE, THERE ARE NO SUBSTANTIAL AND COMPELLING STATE INTERESTS OVERRIDING THE PATIENT'S INDIVIDUAL RIGHT OF PRIVACY.

This honorable Court can, with propriety, address itself to the constitutional aspects of the case before it, because of the Constitution's uncertain application to the facts of this case, and the great numbers of persons upon whom the determination of such constitutional issues will have heavy impact. On page 9 of this brief was set forth an estimate of the number of persons now using Laetrile and to whom its continued use constitutes literally a matter of life or death.

In the present case, what is basically involved is the right of a terminal cancer patient, acting under the direction of his physician, and being fully advised in the premises, to make his own choice of treatment for his fatal disease, in the desparate hope that the treatment of his choice (in this case Laetrile) might succeed in reducing the hideous probabilities that his disease will prove fatal, or if it does not so succeed, then that it might at least bring him a surcease from his physical

suffering. This right of choice in matters involving the health and care of one's own body is a very important application of the broad right of "privacy" which is becoming increasingly dear to human beings who find themselves living in a world of increasingly diminished privacy.

In the case of *People* v. *Privitera*, 141 California Reporter 764 (1978), which involved a criminal action against a doctor whose administering of Laetrile to his cancer patients was deemed in violation of the California Statue forbidding non-approved cancer remedies, the court said, on page 786:

> Historically this right of privacy was first articulated as constitutional right in *Griswold* v. *Connecticut*, 381 U.S. 497, 85 S. Ct. 1678, 14 L. Ed.2d 510, a decision holding unconstitutional a statue prohibiting the use of contraceptives. However, the recognition of the existence, innate in every human being, of a zone of privacy is older than the Bill of Rights, older than our political parties, older than the state's concern with the nature of treatment to be received by cancer-ridden patients. It is in the nature of man that such right exists.
>
> This principle, now of constitutional dimension, has been embraced by many decisions in a variety of situation. (See *In re Lifschutz*, 2 Cal. 3d 415, 432,fn. 12, 85 Cal. Rptr. 829, 467, P. 2d 577 and *Roe* v. *Wade*, 410 U.S. 113, 151-153, 93 S.Ct. 705, 726, 35 L. Ed. 2d 147). This concept, when placed in the doctor-patient relationship is the "right to decide independently, with the advice of his physician, to acquire and to use needed medication." (*Whalen* v. *Roe*, 429 U.S. 589, 97 S.Ct. 869,876,878, 51 L. Ed. 2d 64; *Doe* v. *Bolton*, 410 U.S. 179, 197, 93 S.Ct., 739, 750, 35 L. Ed. 2d 201.)

> *In re Lifschutz*, supra 2 Cal.3d 415,431, 432, 85 Cal. Reptr. 829, 840, 467, P. 2d 557, 568, makes this profound insight concerning *Griswold*:
>
> > Indeed, the decision's concern for valued aspects of individual privacy may ultimately aid in protecting man from the dehumanization of an ever-encroaching technological environment.

The fundamental nature of the right of privacy derives from the very nature of man himself. This thought was clearly expressed by Justice Brandeis in *Olmstead* v. *United States*, 277 U.S. 438, 478, 48 S.Ct. 564, 572, 72 L.Ed. 944 in the following language:

> The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone------the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation. . . .

Judge Cardozo in *Schloendorff* v. *Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92, at 93, stated:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body.

There is no question but what, as a general rule, the state has the right to regulate the delivery of health

services, *Barsky* v. *Board of Regents of University*, 347 U.S. 442, 449, 74 S.Ct. 650, 654, 98. L.Ed. 829; *People* v. *Nunn*, 46 Cal.2d 460, 469, 296 P.2d 813. It is generally conceded that doctors may be prohibited from administering certain types of harmful or habit-forming drugs, under certain circumstances, *Blinder* v. *Division of Narcotic Enforcement*, 25 Cal. App. 3d 174, 101 Cal. Rptr. 635. To put it simply, the Courts recognize the State's interest, pursuant to its legitimate exercise of police power, to discourage or restrain self-injury or suicide. However, in the exercise of this power the means used must be reasonably necessary for the accomplishment of that public purpose, *Goldblatt* v. *Town of Hempstead, New York*, 369 U.S. 590, 594, 595, 82 S.Ct. 987, 990, L.Ed.2d 130.

Judge Bohanon, in his opinion, said at p. 1299:

> While the Constitution does not explicitly mention a right of personal privacy, it is unchallengeable "that a right of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution." *Roe* v. *Wade*, 410 U.S. 113, 152, 93 S. Ct. 705, 726, 35 L.Ed. 2d 147 (1973). This right has been discerned within the penumbras of the Bill of Rights, and specifically within the language of the First, Fourth, Fifth, Ninth, and Fourteenth Amendments to the Constitution, *Roe* v. *Wade, supra,* ". . . only personal rights that can be deemed 'fundamental' or 'implicit' in the concept of ordered liberty,' . . . are included in this guarantee of personal privacy."
>
> Mr. Justice Douglas referred to "the freedom to care for one's health and person" as coming within the purview of this right. *Doe* v. *Bolton*, 410 U.S' 179, 213 (1973), 93 S.Ct. 789, 758, 35 L.Ed.2d 201 (concurring opinion). "The right of privacy,"

> Justice Douglas proceeded, "has no more conspicuous place than in the physician-patient relationship. . . ." *Doe, supra* at 219, 93 S.Ct. at 761. He concluded: "The right to seek advice on one's health and the right to place reliance on the physician of one's choice are basic. . . ." *Doe, supra.*

A. Laetrile is Safe, and Not Dangerous to Human Health

This brief does not question the right and duty of the FDA to promulgate reasonable regulations proscribing trafficking in drugs which are considered unsafe or dangerous to human health when taken under the conditions prescribed, recommended, or suggested in the labeling thereof. However, the safety, or non-toxicity of Laetrile cannot be reasonably called into question. Judge Bohanon, when this case was first before him, found, at page 1212:

> The Court finds from the record, testimony and exhibits, that laetrile is not lethal in any sense of the word. It is not harmful to the human body and when used in proper amounts under proper control and supervision can effect relief from cancer disease to the satisfaction of many who are privileged to use the same.

The Court in *People* v. *Privitera, supra*, found, on page 778, that:

> "It [Laetrile] is generally conceded to be a harmless drug."

and again, on page 767:

> "It is generally conceded that amygdalin is nontoxic; it does not fall within the general ban of drugs which are toxic, habit forming, addictive, or otherwise distort reality."

Judge Bohanon, in his second decision in the instant case found, on page 1295:

> The record and the law reasonably support but one conclusion: Laetrile (Amygdalin) has been commercially used and sold in the United States for the treatment of cancer for well in excess of 25 years, during which time it has been "generally recognized" by qualified experts as safe for such use. . . . [page 1297] The administrative record brooks little real controversy as to Laetrile's nontoxicity, particularly when administered parenterally, even at doses greatly exceeding amounts normally ingested.

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[23] In the only laboratory study of record specifically designed to determine the drug's toxicity, it was observed: "Amygdalin, at all doses studied, appears to be completely non-toxic in laboratory mice." Harold W. Manner, Ph.D., Chairman, Department of Biology, Loyola University, Chicago, Illinois (R 262). Of the various controversial tests studying Laetrile's efficacy on animal tumors, none have disclosed toxicity at reasonable dosage levels.

Among the numerous scientists and physicians testifying from first-hand experience with Laetrile and its effect on humans, unanimity exists as to its nontoxicity.

Dr. Phillip Binzel, M.D., graduate of St. Louis University, testified that he has personally given nearly 4,000 intravenous injections of Amygdalin using doses up to 9 grams without any adverse reaction. (tr. 363).

Daniel S. Martin, M.D., who participated in the same Sloan-Kettering experiments in which Dr. Sugiura detected cancer inhibiting properties in Laetrile, and who disputed Dr. Sugiura's results,

nonetheless concluded that there was no doubt that Laetrile was nontoxic, at least if administered parenterally. (Tr. 437).

Charles Gurchot, Ph.D., testified for the record in affidavit form that Amygdalin in liquid and solid form was used prior to 1962 (between 1934 and 1945) by Gurchot, under supervision of five named medical doctors at the University of California Medical School at San Francisco. This Amygdalin was, according to his statement, administered "on patients intramuscularly and intravenously." He further stated that during this same period Amygdalin was being used to his personal knowledge by approximately a dozen California physicians in their treatment of cancer. Gurchot expresses his belief that Amygdalin was generally recognized by experts as being safe for use in the treatment of cancer on or prior to October 10, 1962. (R 302 at J-206).

Chauncey D. Leake, Ph.D., indicated in his affidavit that he is familiar with Dr. Gurchot's use of Amygdalin in the mid 1930's and 1940's at the University of California Medical School Hospital in San Francisco. He further indicates that physicians and other scientists familiar with Amygdalin recognized it as safe at that time. (R 302 at J-200).

Dr. Dean Burk, former head of the Cytochemistry Section, National Cancer Institute, Bethesda, Maryland, after testing Amygdalin on rats, says the substance is "notably less toxic to animal organisms than ordinary diet sugar," and that aspirin tablets are 20 times more toxic than an equivalent amount of Amygdalin (R 183 at 166F).

> Investigators have found that intravenous doses in excess of 20 grams have been without toxic effect in healthy human subjects, although occas-

sionally a mild hypotensive effect may be observed. Repeatedly, studies have indicated that pure Amygdalin, when administered parenterally is astonishingly devoid of toxic effects. (R 163 at 166F).

Donald C. Thompson, M.D., of Morristown, Tennessee, testified as to his personal experience with administering Laetrile to patients and affirmed the drug's nontoxicity. (R 515).

In his report entitled "Use of Laetrile in the Prevention and Treatment of Cancer," Dr. David Rubin, M.D., surgeon at Beilinson Hospital and cancer researcher at Hadassah Hospital in Jerusalem, Israel, asserts: "Laetrile is nontoxic even in very large injected doses." (R 510, Ex. 12).

As another example of a practicing physician who has extensively used Amygdalin and determined it to be nontoxic, see the letter of The Honorable Lawrence P. McDonald, Congressional Representative from Georgia. (R509 at N265-68).

> 'Amygdalin (Laetrile) is totally non-toxic systemically, at commonly applied dosages.' Hans A. Nieper, M.D., Hannover [sic], West Germany. (R 302 at J-180).

While a doctor's inability to control many variables potentially relevant to curing a disease may impugn the credibility of his perceptions as to a drug's efficacy (see *Weinberger* v. *Hynson, supra*) his observations as to its toxicity are much more reliable, since the relevant variables are more manageable.

> "[Laetrile] is totally nontoxic. Its lethal dose in mice and rats, by injection, is about 25,000 miligrams per kilogram of body weight. It is so nearly nontoxic that in some studies the water,

> used as a dilutant presents a greater toxicity than the vitan in." *The Journal of Applied Nutrition*, Ernst T. Krebs, Jr. (R 302 at J-187).
>
> ". . . All the available facts indicate that Amygdalin is essentially non-toxic to laboratory animals and to humans." Raymond Ewell, Ph.D. in chemistry from Princeton, retired professor from the State University of New York, at Buffalo. (R 302 at J-196).

Dr. John A. Richardson, previously referred to, in his book "Laetrile case histories" (1977), says, on page 23:

> One of the reaons given for refusing is that Laetrile might be toxic. They [the F.D.A.] said:
>
> 'It is dangerous to initiate human studies while the nature of the toxicity has not been elucidated in large animal species.'
>
> To anyone with any knowledge of the subject at all, that is an incredible statement. Amygdalin has been well known and listed in the *United States Pharmacopeia* as a non-toxic substance for over a hundred years. The human case studies submitted by McNaughton were further proof of its safety. To deny permission to test on the grounds that amygdalin *may* be toxic is mind-boggling when one realizes that virtually all drugs currently approved by the F.D.A. for cancer therapy are *extremely toxic.*

B. Laetrile is a Reasonable and Relatively Effective Cancer Remedy, vis-a-vis its State-Sanctioned Alternatives. "Effective," in this Context, has Reference, not only to Controlling or Curing Cancer, but Providing other Substantial Benefits to the Patient, such as Decreased Pain, Improved Quality of Life, and Avoidance of Excruciating, and Expensive, State-Sanctioned Alternative Remedies.

This Court is not called on, of course, to place a final evaluation on the claims on behalf of Laetrile, vis-a-vis its state-sanctioned alternatives. It is entitled, however, to satisfy itself, from the evidence contained in the record, that there is enough testimony in favor of Laetrile to indicate that it has at least crossed a sufficiently acceptable threshold of rationality to indicate that the patient's preference for it is neither suicidal nor irrational .

We have, here, a clear collision between two conflicting doctrines: the one declaring that the state has a legitimate interest in preventing people from seriously injuring or killing themselves, and the other declaring that people should be free to choose their own form of therapy. Where to draw the line between those two doctrines is what this case is all about.

The FDA faces a particular difficulty in relating its proscriptions of Laetrile to the first doctrine above mentioned (protecting people from self-injury). The reason for this is that the respective risks and benefits of the State-sanctioned remedies (surgery, radiation and/or chemotherapy), and those of the State non-sanctioned remedy (Laetrile) are almost impossible to compare by

any objective and generally-agreed-upon standard of comparison. If State-sanctioned remedies were to lead to complete, or virtually complete, recovery from cancer, and if Laetrile were to lead to certain, or virtually certain death or risk of death, the legal issue would be clear-cut and simple. The actual facts are, however, that the results of the State-sanctioned remedies, viewed in their most favorable light, are woefully disappointing (only one out of three cancer patients currently alive will still be alive in five years), and the results of Laetrile are sharply controverted, the government arguing that the Laetrile patient's chances of recovery are considerably less than those associated with State-sanctioned remedies (or even nonexistent), and the proponents of Laetrile arguing that they are considerably better.

It must not be forgotten, moreover, that the measure of the value of Laetrile is not alone the high percentage of recovery from, or complete control of, the disease for which Laetrile can claim credit, as opposed to the lesser percentage attainable under state-sanctioned remedies, but the additional benefits which Laetrile offers, such as a certain but unmistakable diminution of pain, plus the offering to the patient of a course of treatment that avoids for him the hideous consequences of surgery, radiation, and/or chemotherapy.

In consideration of these realities, therefore, it can be reasonably argued that the reasons for imposing by law the state-sanctioned remedies, and for outlawing Laetrile, become so weak, that at this point the law's strong penchant for protecting the individual's right of privacy should be sufficient to tip the scales in favor of giving the patient his freedom of medical choice. Under the above circumstances, it can hardly be argued

that compelling and substantial reasons require giving the State-sanctioned remedies the status of an absolute monopoly.

The case for Laetrile is made even stronger since it can be established that it involves no toxicity whatsoever (in contradistinction to the State-sanctioned alternatives which involve a high degree of toxicity, or, in the case of surgery, bodily injury), and since the patient is acting under the direction of a personal physician who understands his needs far better than does the State, which can deal only in generalities, and which physician can be expected to take care of the State's interest in not allowing the patient to embark on a suicidal course, and since it can be clearly shown to be in society's best interest that more flexibility be given in the use of nontoxic drugs, to encourage that kind of generalized use which alone can resolve the baffling question of their efficacy.

It follows, therefore, that it becomes proper, at this point, to establish, from the record, and from other credible sources, that the Laetrile treatment can show a better record of recovery than can so-called State-sanctioned alternatives.

The District Court, when this case was first tried before it, found, as reported on page 1212:

> The Court finds from the record, testimony and exhibits, that laetrile is not lethal in any sense of the word. It is not harmful to the human body and when used in proper amounts under proper control and supervision can effect relief from cancer disease to the satisfaction of many who are privileged to use the same.

During the second trial of this case in the District Court, Judge Bohanon found that not only was Laetrile's

safety not subject to the slightest doubt, but that a considerable array of competent physicians had already expressed themselves as favorable to its use. Admittedly, the overwhelming consensus among orthodox practioners was against Laetrile. However, the weight to be given this negative consensus was considerably reduced, according to Judge Bohanon, by the fact that many of those who were most vociferous against Laetrile betrayed only a superficial familiarity with it, in contrast to its advocates, whose advocacy generally was born of familiarity with actual case histories of success.

The Court said, on page 1292:

> Unquestionably, the administrative record in this case reveals a substantial and well-developed controversy among medical professionals and other scientists as to the efficacy of Laetrile.
>
> Advocates of Laetrile's use in cancer treatment include many highly-educated and prominent doctors and scientists,[9] whose familiarity and practical experience with the substance vastly exceeds that of their detractors. To deem such advocacy "quackery" distorts the serious issues posed by Laetrile's prominence and requires disregarding considerable expertise mustered on the drug's behalf.
>
> While the record reveals an impressive consensus among the nation's large medical and cancer-fighting institutions as to Laetrile's ineffectualness, a disconcerning dearth of actual experience with the substance by such detractors is revealed.

The footnote 9, referred to in the above quoted passage, reads as follows:

> [9] Proponents of the use of Laetrile include:
>
> Dean Burk, Ph.D. in biochemistry from the University of California. A research scientist possessing 35

years' experience with the National Cancer Institute, Dr. Burk is the former head of the Institute's Cytochemistry Section. (R. 302; Tr. 401).

Charles Gurhcot, Ph.D. in chemistry and physiology from the Cornell University, former assistant professor of Pharmacology, University of California Medical School at San Francisco. (R. 302 at J-206).

Chauncey D. Leake, Ph.D., former associate professor of pharmacology at University of Wisconsin (R. 302 at J-200).

Raymond Ewell, Ph.D. in chemistry from Princeton. (R. 302 at J-196).

Phillip Binzel, M.D., (Tr. 360); John A. Richarson, M.D. (R. 510, Ex. 1 and Tr. 462); The Honorable Lawrence R. McDonald, (R. 509); Ernst T. Krebs, Sr. M.D., and Dr. Ernst T. Krebs, Jr. (Tr. 228); perhaps as many as 600 American M.D.'s or more have employed and are advocating the use of Laetrile in cancer treatment (R. 313 at J-255).

David Rubin, M.D., surgeon at Beilinson Hospital and cancer researcher at Hadassah Hospital in Jerusalem, Israel. (R. 510, Ex. 12).

Mario Soto, M.D., of Mexico, authorized by the National Cancer Institute to conduct independent investigational studies with the Institute's cancer drugs. (R. 286, Tr. 478.)

Hans A. Nieper, M.D., Hanover, West Germany; Ernest Contreras, M.D., Tijuana, Mexico; Shigeaki Sakai, M.D.; of Tokyo, Japan; Etore Guidetti, M.D. Brazil. (R 507).

Many doctors testify that Laetrile can confer an "improved quality of life" even upon patients who ultimately die, by reducing their pain and discomfort. For example, see P.E. Binzel, Fr., M.D., (Tr. 362); David Rubin, M.D. (R 510, Ex. 12).

There are even some members of the nation's leading cancer institutions who have voiced no objections to the use of Laetrile under proper circumstances. For example, at R 195 of the record transcript, appears an affidavit, referred to by Judge Bohanon in footnote 10, on page 1293, of C. Chester, Ph.D., vice-president and associate director for administrative and academic affairs of the Sloan-Kettering Institute for cancer Research, New York, in which he says: "I have stated before,. . . that if the patient has exhausted the benefits of conventional treatment and does not mind the financial outlay, I see no harm in his taking Amygdalin in the way it has generally been used."

Despite the assertion of the FDA that there are no known tests conducted on mice which show Laetrile to have had any positive results, the facts are that many such tests have been conducted showing positive results. Judge Bohanon, in footnote 13, page 1294 of his opinion, states:

> Knowledgeable experts have expressed sharp criticism of certain prominent Laetrile tests on animals in which the substance was determined ineffective. Note the analyses of Dr. Bernard Kenton of the City of Hope National Medical Center, Los Angeles, California (R 507 at N 249); and Dr. Dean Burk (R302 at J-117); also those of Dr. Michael Fox, chairman of the Biomathematics Department of the City of Hope National Medical Center and assistant professor of biomathematics at UCLA, and Harold Hornsby, research scientist with NASA and a Fellow of the Royal Statistical Society in London (R 313 at J-253 and 254). Sloan-Kettering researcher Dr. Kanemasto Sugiura performed at least six different tests in which he concluded that Laetrile was effective in combatting certain types of

tumors; the Institute subsequently released other test results reportedly contradicting Dr. Sugiura's findings. Dr. Suguira is quoted as saying: 'It is still my belief that amygdalin cures matasteses". (R 313 at J-241).

The California Court of Appeals, in the case of *People* v. *Privitera, supra*, on page 767, had this to say about the use of Laetrile to avoid the risks involved in conventional therapy:

> Dr. Privatera points out that many cancer victims have investigated and evaluated the merits of surgery, radiation therapy, or chemotherapy with the aid of competent medical advice and have made the highly personal decision: The benefits from such therapy are not sufficient to justify the risks which include disfigurement, debilitation, and accelerated death, and for this reason have chosen to seek amygdalin as a treatment; other cancer victims have been advised that their condition is hopeless, their case is terminal and as a last resort before certain death, seek amygdalin.

Dr. Dean Burk, previously referred to, in his booklet "Vitamin B-17—a Brief on Foods and Vitamins", published by the Dean Burk Foundation, Inc., publication No. 1, 1975, reviews five carefully controlled experiments on mice that have shown definite Laetrile anticancer action. The following is quoted from his booklet, p. 15:

> AMYGDALIN EFFICACY IN ANIMAL SYSTEMS
>
> Anticancer vitamin activity by amygdalin (laetrile) has been observed in a wide variety of animal cancers, with high statistical significance, in more than five independent research institutions in three

widely separated countries of the world, including e.g.:

(1) Sloan-Kettering Cancer Center (New York), with CD_8F_1 mice bearing spontaneous mammary carcinomas: inhibition of formation of lung metastases, inhibition of growth of primary tumors, and greater crystalline amygdalin/kg body weight/day (Report of K. Sugiura, June 13, 1975).

(2) Southern Research Institute (Birmingham, Alabama) for the National Cancer Institute, in a majority of 280 BDF_1 mice bearing Lewis lung cancers, treated with up to 400 mg crystalline amygdalin per kg body weight, with respect to increased life span (Report, December 3, 1974).

(3) Scind Laboratores, University of San Francisco, 400 rats bearing Walker 256 carcinoma (200 treated with amygdalin, 200 controls), with 80% increase in life span at optimum dosage (500 mg amygdalin/kg body weight) (October 10, 1968). Cf. FDA-IND application No. 6734. pp. 247-8, 00080-00093. NCI Director Carl Baker wrote Congressman Edwin W. Edwards on Jan. 26, 1971: "The data provided by the McNaughton Foundation certainly indicates some activity in animal tumor systems" (emphasis added).

(4) Pasteur Institute (Paris), with human cancer strain maintained in mice treated at optimal dosage of 500 mg Amygdalin Marson/kg body weight/day; increased life span and delayed tumor growth up to 100% (Dec. 6, 1971 report by M. Metianu).

(5) Institut von Ardenne (Dresden, Germany), H strain mice bearing Ehrlich ascites carcinoma treated with bitter almond amygdalin ad libitum in addition to the regular chow diet: increased life span and decreased rate of cancer growth, treatment

beginning 15 days before cancer inoculation (Arch. Geschwulstforsch. 42, 135-7 1973).

Dr. Hans Nieper, M.D. Director of the Department of Medicine at Silbersee Hospital in Hanover, Germany, who is listed in *Who's Who in World Science,* who is Director of the German Society of Medical Tumor Treatment, and who has had many years of personal experience with Laetrile (amygdalin), told newspaper reporters as long ago as 1972, the following:

> After more than twenty years of such specialized work, I have found that non-toxic Nitrilosides—that is, Laetrile—are far superior to any other known cancer treatment or preventative. In my opinion it is the only existing possibility for the ultimate control of cancer.

In Canada, N.R. Bouziane, M.D., Director of Research Laboratories at St. Jeanne d'Arc Hospital in Montreal, member of the hospital's tumor board in charge of chemotherapy, a *magna cum laude* graduate in medicine from the University of Montreal, an affiliate of Oxford University in New Brunswick, a fellow in chemistry and a fellow in hematology, and certified in clinical bacteriology, hematology, and biochemistry from that college, after making a series of tests with Laetrile shortly after it was introduced, reported:

> We always have a diagnosis based on histology [microscopic analysis of the tissue]. We have never undertaken a case without histological proof of cancer. . . .
>
> In our investigation, some terminal cases were so hopeless that they did not even receive what we consider the basic dose of thirty grams. Most cases, however, became ambulatory and some have in this

> short time resumed their normal activities on a maintenance dose. *Cancer News Journal*, Jan./April, 1971, p. 20.

In the Philippines Manuel Navarro, M.D., is professor of medicine and surgery at the University of Santo Tomas in Manila. He is an Associate Member of the National Research Council of the Philippines; a Fellow of the Philippine College of Physicians, and of the Philippine Society of Endocrinology and Metabolism; and a member of the Philippine Medical Association, the Philippine Cancer Society, and many other medical groups. He has over one hundred scientific papers to his credit, some of which have been read before the International Cancer Congress. In 1971 Dr. Navarro wrote:

> I . . . have specialized in oncology [the study of tumors] for the past eighteen years. For the same number of years I have been using Laetrile-amygdalin in the treatment of my cancer patients. During this eighteen-year period I have treated a total of five hundred patients with Laetrile-amygdalin by various routes of administration, including the oral and the i.v. The majority of my patients receiving Laetrile-amygdalin have been in a terminal state when treatment with this material commenced.
>
> It is my carefully considered clinical judgment, as a practicing oncologist and researcher in this field, that I have obtained most significant and encouraging results with the use of Laetrile-amygdalin in the treatment of terminal cancer patients, and that these results are comparable or superior to the results I have obtained with the use of the more toxic standard cytotoxic agents. *Cancer News Journal*, January/April, 1971, pp. 19, 20.

In Mexico, Ernesto Contreras, M.D., has operated the Good Samaritan Cancer Clinic in Tijuana for over a decade. He is one of Mexico's distinguished medical figures, having received postgraduate training at Harvard's Children's Hospital in Boston. He has served as Professor of Histology and Pathology at the Mexican Army Medical School and as the chief pathologist at the Army Hospital in Mexico City.

Dr. Contreras was introduced to Laetrile in 1963 by a terminal cancer patient from the United States, who urged him to treat her with it. The patient recovered, and so impressed Dr. Contreras, that he spent considerable time and effort in investigating Laetrile's properties. Since that time he has treated thousands of cancer patients, most of whom are American Citizens who have gone to Mexico to obtain what they were denied in the United States.

Dr. Contreras has summarized his experiences with vitamin (principally B-17) therapy as follows:

> The palliative action [improving the comfort and well-being of the patient] is in about 60% of the cases. Frequently, enough to be significant, I see arrest of the disease or even regression in some 15% of the very advanced cases. *Cancer News Journal*, Jan./April, 1971, p. 20.

Dr. Shigeaki Sakai, a prominent physician in Tokyo, in a paper published in the October 1963 *Asian Medical Journal*, reported:

> Administered to cancer patients, Laetrile has proven to be free from any harmful side-effects, and I would say that no anti-cancer drug could make a cancerous patient improve faster than Laetrile. It goes without saying that Laetrile controls cancer and is quite effective wherever it is located.

In a recent statement, Arlin J. Brown, Director of the Arlin J. Brown Information Center, and a long-time student of cancer and its causes, said the following:

> Laetrile is so effective in the prevention of cancer that no cases have ever been reported in individuals who ingest Laetrile and/or apricot kernels on a regular basis. . . . In the Asian country of Hunza . . . the average Hunzakut native normally consumed over 100 apricot kernels daily—and cancer is totally non-existent in that area. . . . The preventive nature of apricot kernels has also been scientifically demonstrated in the laboratory. Dr. Vern van Breeman, a biologist at Salisbury State College in Maryland, has shown that when mice, especially bred to develop cancer, are given apricot kernels, the cancer prevention rate is well over 90%. . . . All control mice developed cancer and died. Mice with leukemia lived 50% longer when given apricot kernels.

Dr. David Rubin, a surgeon and cancer researcher at Hadassah Hospital in Jerusalem, after 15 months of Laetrile research on terminal patients, stated:

> The most striking observable feature was relief from pain accompanied by a decrease or even cessation of the need for pain killers and sleeping potions. In the majority of cases the patients came off long term use of narcotics without the usual withdrawal symptoms. After a few days of treatment with Laetrile there was an improvement in appetite, followed, in many cases, by a gain in weight. A frequent striking feature in

cancer wards is the odor of decaying cancer masses. We observed that this odor is generally absent in the cases under Laetrile therapy.

Testimonials favorable to Laetrile from other physicians are also readily obtainable. These include Professor Estore Guidetti, M.D., of the University of Turin Medical School, Italy; Professor Joseph H. Maisin, Sr. M.D., of the University of Louvain, Belgium, where he is Director of the Institute of Cancer; the late Dr. John A. Morrone of the Jersey City Medical Center, and many others.

The aforenamed Dr. Contreras, with his associates Drs. Abel Mellado Prince, and Dr. Jose Ernesto Contreras Pulido, recently analyzed retrospectively the charts on 1,200 cancer patients [most of whom were from the United States] to whom they had administered Laetrile. As indicated, most of them were in advance stages of cancer, i.e., were terminal cases. Only 1.1 percent had not received previous therapy.

The following report shows the results of their analysis:

AMYGDALIN. A NEW ANTI-TUMOR AGENT
PHASE II STUDIES

DR. ERNESTO CONTRERAS RODRIGUEZ*
DR. ABEL MELLADO PRINCE*
DR. JOSE ERNESTO CONTRERAS PULIDO*

SUMMARY. 1,200 charts of patients with proven

*From the Staff of Del Mar Medical Center and Hospital Playas de Tijuana, Baja Calif., Norte, Mexico.

malignant diseases were analyzed retrospectively. 32 different tumors were studied, the more frequent being rectum and colon (224 cases), lung (192 cases) and breast (180 cases). 86.7% of patients had extensive disease and tumor activity. Only 14 patients (1.1%) were received without previous therapy. All the patients received Amygdalin as the only anti-tumor agent for a minimum of 4 weeks and until—change of program or death. The subjective response was good in 65.1%, regardless of the stage and condition of the patients. Objective response was demonstrated in 32.6% of the cases. These were distributed as follows: Total remission 3.6%; partial remission 7.1%; improvements 12.3% and stabilizations 9.6%. The best responses were observed in carcinoma and lymphoma. Among the carcinomata, the best responders were bronchogenic, prostate, stomach and breast in postmenopausal women. These results, we believe, justify the clinical use of Amygdalin in advanced malignant disease. Prospective comparative studies (Phase III) should be planned for the more responsive tumors.

The said chart shows:

1. Practically all cancer patients treated had received previous therapy, and had gone to Laetrile, presumably because of their lack of faith or hope in the therapy previously received.
2. 86.7 percent had "extensive" disease and tumor activity.
3. Approximately 2/3 of the patients showed improved subjective response. In other words, they felt better.
4. Approximately 1/3 could show objective improvement.

5. Of that number, 3.6 percent showed total remission, and 7.1 percent partial remission; and 12.3 percent showed some improvement. Considering that these patients were presumably all terminal, 99 percent of whom had had previous treatment and were dissatisfied with the results, these results are impressive.

The number of cases where Laetrile has resulted in granting either a complete cure or a permanent "control" of the disease to cancer patients previously diagnosed as terminal, is impressive. No one knows the number, but it is far higher than can be explained on the theory of "spontaneous regressions". Dr. John A. Richardson, in his book "Laetrile Case Histories", (1977), discusses this point in the following language:

> So, as a final resort, a last-ditch effort to discredit Laetrile, especially in those cases where there has been no prior orthodox therapy for the supposed delayed reaction, the critics finally fall back to the claim that these cases represent "spontaneous regressions," that the cancer just went away on its own, not as a result of Laetrile, but as a result of a return of the natural resistance of the host.
>
> It is true that occasionally a patient will recover from cancer without any treatment whatsoever. This fact tells us something important. It tells us that the body *does* have some kind of *natural* control for the disease, if we only knew what it was. One thing is certain, whatever it is, it is *not* X-radiation or toxic chemicals.

> The statistical probability for spontaneous regressions is just about the same as for delayed reactions. Most official estimates are 1 in 80,000 to 100,000 cases. [7] Warren Cole, Emeritus Professor of Surgery at the University of Illinois College of Medicine, reviewed the spontaneous remission cases reported in all the medical journals from 1960 to 1966. Including cases dating back to the early 1900's there were exactly 92 cases that had a survival rate of two years or more. [8]
>
> If these really are cases of spontaneous remission, then it should be noted that I have more such cases at my own clinic than the rest of the world combined. It would seem that we get a much higher rate of "spontaneous remissions" using Laetrile than with anything else we've tried!

Ms. Gertrude Engel, previously referred to, in a prepared statement given before the Subcommittee on Health and Environment of the House Committee on Interstate and Foreign Commerce, on June 21, 1978, [which information was repeated before Senator Edward M. Kennedy, Chairman of the Senate Subcommittee on Health and Scientific Research] said the following:

> Alicia Buttons, who was declared dying six years ago, also travels to Germany to receive treatment from D. Nieper. She is the wife of Red Buttons, famous actor comedian. I have been in constant touch with Alicia Buttons. I met them several years ago. Alicia was told she would pass away

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[7] "Spontaneous Regression of Cancer: The Metabolic Triumph of the Host?" *Annals of the New York Academy of Science*, Vol. 230, op. cit. pp. 111, 112.

[8] Ibid., p. 112.

> because she had cancer of the lymph nodes, and Red Buttons took her to Germany to meet with Dr. Hans Nieper [for Laetrile treatment].

Mr. Buttons, in a public declaration to the world made just a few months ago, said, in this regard:

> Six and a half years ago, . . . I got the news: "Red, your wife has cancer and it's very bad." The prognosis was: "With luck, she might be able to live a year."
>
> That was six and a half years ago. I'm delighted to tell you that six and a half years after, my wife is fine and healthy and happy—thanks to something that has been condemned as a hoax and a fraud. That something is called LAETRILE.

Ms. Engel, in her aforementioned testimony before the House subcommittee, made two additional statements which are worthy of special note. First, she quoted Dr. Arthur Upton, who is Director of the National Cancer Institute, as follows: "There are, right now, in our files, over 200 cases of those people taking Laetrile, and very successfully."

She then quoted Dr. Donald Frederickson, Director of the National Institutes of Health, who said: "For the National Institutes of Health to say that Laetrile is worthless is wrong. We are trying to be objective."

In spite of the reluctance of Laetrile proponents to ever claim that Laetrile can invariably cure or control cancer, the fact remains that in many publicized and well-documented cases it has done just that. Some of these stories are deeply moving and highly dramatic. In spite of the reluctance of Laetrilists to build their case for Laetrile on the strength of these isolated, or, as the FDA calls them, "anecdotal" cases, their frequency seems to have defied every anti-Laetrile explanation. Various authors have from time to time, gathered together some of these stories, and they are easily available.[9]

As long as these exciting stories continue to be generated—stories that bring hope to otherwise despairing and condemned persons—and as long as a legal cloud still hovers over the use of Laetrile, there will remain a general disappointment which absolutely nothing that the law can do, other than the complete legitimizing of Laetrile, can ever hope to dispel.

Laetrilists are not dogmatists. It would seem prudent to grant to the use of Laetrile the same room for growth and development as has been so assiduously reserved by the law for other treatments which have now (but had not at the beginning), attained respectability.

It must also be recalled that the success or failure of the Laetrile treatment depends in large measure on associated factors such as: the willingness of the patient

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[9] See, for example, "Laetrile Case Histories" by John A. Richardson, M.D. and Patricia Griffin, R.N., previously referred to.

to submit to a rigid dietary regime, the ingestion of other vitamins and enzymes, etc. Doctors are more and more realizing that the restructuring of a patient's metabolic system involves a multitude of factors, of which only one, albeit an important one, is the ingestion of heavy concentrations of vitamin B-17.

At the second trial of this case before Judge Bohanon, P.E. Binzel, Jr., M.D., testified, (tr. 363):

> I know of no doctor throughout the world who is now using Amygdalin who does not agree that the maximum benefit from Amygdalin is obtained when it is used in combination with other vitamins, enzymes, and proper diet.

In spite of the FDA's intense antagonism to Laetrile, and to the medical rationale underlying it, it is interesting to note, here and there, a begrudging concession by the FDA to some of the Laetrilists' major premises. For example, with regard to the premise that cancer is related to dietary deficiency, and particularly vitamin deficiency, (which is one of Laetrilists's major theses), we read, in the FDA's publication "The Cancer Story", 1973 revision, on page 34, the following:

> There is some evidence that vitamin deficiency in man plays a role in the occurrence of cancers of the oral cavity and the esophagus. . . If such deficiency exists, it is probably only one of a number of factors to be considered.

Regarding another of Laetriliests' premises, namely that the body can develop its own system of immunity, the aforementioned "The Cancer Story", on page 46, has the following statement:

> Closely allied to virus research are advances in immunology. We know that many cancers manufacture antigens, to which the body reacts by humeral and cellular immune responses. . . Knowledge in tumor immunology is being rapidly applied to the diagnosis and treatment of cancer.

We now address the disappointing record of so-called state-sanctioned cancer treatments: surgery, radiation, and chemotherapy. Stripped of the latters' aura of respectability, with which time and institutionalization have vested them, their record of success must be recognized as appalling.

Laetrile's record of success, though far from perfect, must not be judged in a vacuum. Any meaningful evaluation must be in the nature of a comparison with available alternatives. Such a comparison leaves Laetrile in by far the better position.

Judge Bohanon addressed this question in footnote 25 on page 1299 of his opinion, as follows:

> Such a decision [to have recourse to Laetrile] is by no means necessarily indicative of suicidal tendencies. Dr. Hardin Jones of the University of California has presented impressive evidence in support of the thesis that in some instances at least untreated cancer victims outlive treated ones. (R 507) Conventional modes of treatment, particularly radiation and chemotherapy, can cause extensive damage to healthy organs and tissues as well as cancerous ones. Some argue that in destroying the body's natural defense mechanisms such approaches often destroy important weapons crucial to an effective fight against cancer and also greatly increase a patient's vulnerability to other life-threatening diseases as well.
>
> Patients possessing particularized complicating factors, such as old age, frail physical constitutions, or certain types of religious convictions, might also understandably decide to forego the rigors of such conventional methodologies.

Even doctors who oppose the use of Laetrile will generally concede as to orthodox modes of treatment (surgery, radiation and chemotherapy): " . . . the treatments that are available are very often disfiguring; they can be painful; they can be unpleasant; they can even be risky." Emil J. Freireich, Professor of Medicine at the University of Texas, School of Medicine, Houston. (Tr. 204)

In attacking the credibility of "cures" reported to have been effectuated by Laetrile, FDA argues that in many such instances the person involved may never even have had cancer. "Even where the diagnosis has been done by someone other than a Laetrile proponent, a mistake is possible. Some cancers which are discussed in reference to Laetrile are very difficult to diagnose histologically. Thus, a diagnosis of cancer may often on later review be reversed." Commissioner's Decision (R 523) at 227). This analysis is hardly reassuring to individuals such as plaintiff Glen Rutherford, whose proposed surgery, a colostomy, would have unalterably lessened the quality of his life, irrespective of the ultimate outcome of his illness. (See *Rutherford* v. *United States*, 399 F. Supp. 1208 (W. D. Okl.1975).

In the volume "World without Cancer", by G. Edward Griffin, 1977 printing, starting on page 172, we read:

> For comparison let us take a look at the results and benefits of the so-called cures obtained through surgery, radiation, and chemotherapy.
>
> As we shall see, surgery is the least harmful of the three. In all fairness it must be said that, in some cases, it can be a life-saving stop-gap measure—particularly where intestinal blockages and adhesions must be relieved in order to prevent the

> patient from dying from secondary complications. Surgery also has the psychological advantage of visibly removing the tumor. And, from that point of view, it offers the patient and his family some temporary comfort and hope. However, the degree to which surgery is useful is the same degree to which the tumor is *not* malignant. The greater the proportion of cancer cells in that tumor, the less likely it is that surgery will help. And the most highly malignant tumors of all generally are considered inoperable.
>
> A further complication of surgery is the fact that any cutting into the tumor—even a biopsy—does at least two things that logically should aggravate the condition. First, it causes physical trauma to the area. . . The other effect is that, if not all the malignant tissue is removed, what remains tends to be encased in scar tissue from the surgery. Scar tissue tends to act as a barrier between the cancer cell and the rest of the body . . .
>
> Perhaps the greatest indictment of all against surgery is the knawing suspicion among even many of the world's top surgeons that, statistically, there is no solid evidence that patients who submit to surgery have any greater life expectancy on the average, than those who do not. This is an area which desparately needs intensive and unbiased study.
>
> The first statistical analysis of this question was compiled in 1844 by Dr. Leroy d'Etoilles and published by the French Academy of Science. It is, to date, the most extensive study of its kind ever released. Over a period of thirty years, case histories of 2,781 patients were submitted by 174 physicians. The average survival after surgery was only one year and five months—not much different than the average today.

Dr. Leroy d'Etoilles separated his statistics according to whether the patient submitted to surgery or caustics, or refused such treatment. His findings were electric:

> The net value of surgery or caustics was in prolonging life two months for men and six months for women. But that was only in the first few years after the initial diagnosis. After that period, those who had not accepted treatment had the greater survival potential by about fifty percent.[1] [Footnotes to Griffin material appear on p. 61]

1844, of course, was a long time ago. But recent surveys invariably have produced nearly the same results. For instance, it long has been accepted practice for patients with breast cancer to have not only the tumor removed but the entire breast and the lymph nodes as well. In more recent years, the procedure often includes removal of the ovaries also on the theory that cancer is stimulated by their hormones. Finally, in 1961, a large-scale controlled test was begun, called the National Surgical Adjuvant Breast Project. After seven-and-a-half years of statistical analysis, the results were conclusive: There was no significant difference between the percentage of patients remaining alive who had received the smaller operation and those who had received the larger.[2]

One of the most distinguished statisticians in the medical field is Hardin B. Jones, Ph.D., professor of medical physics and physiology at the University of California at Berkeley. After years of searching published and unpublished clinical records, he appeared at an American Cancer Society convention and reported bluntly:

> In regard to surgery, no relationship between intensity of surgical treatments and duration of survival has been found in verified malignancies.

> On the contrary, simple excision of cancers has produced essentially the same survival as radical excision and dissection of the lymphatic drainage.[3]

All of this, of course, related only to surgery of the breast. Turning his attention to surgery in general, Dr. Jones reported:

> Although there is a dearth of untreated cases for statistical comparison with the treated, it is surprising that the death risks of the two groups remain so similar. In the comparisons it has been asssumed that the treated and untreated cases are independent of each other. In fact, that assumption is incorrect. Initially, all cases are untreated. With the passage of time, some receive treatment, and the likelihood of treatment increases with the length of time since origin of the disease. Thus, those cases in which the neoplastic process progresses slowly [and thus automatically favors a long-term survival] are more likely to become "treated" cases. For the same reason, however, those individuals are likely to enjoy longer survival, whether treated or not. Life tables truly representative of untreated cancer patients must be adjusted for the fact that the inherently longer-lived cases are more likely to be transferred to the "treated" category than to remain in the "untreated until death."
>
> *The apparent life expectancy of untreated cases of cancer after such adjustment in the table seems to be greater than that of the treated cases.*
> [Emphasis added]

What, then, *is* the statistical chance for long-term survival of five years or more after surgery? That, we are told, depends on the location of the

cancer, how fast it is growing, and whether or not it has spread to a secondary point in the body. For instance, two of the most common forms of cancer requiring surgery are of the breast and the lung. In the case of breast cancer, only sixteen percent will respond in any way to either surgery or X-ray therapy. In the case of lung cancer, the percentage of patients who will survive five years after surgery is somewhere between five and ten percent. [4] And these are optimistic figures when compared to survival expectations for some other types of cancers such as testicular chorionepitheliomas.

An objective appraisal, therefore, is that the statistical rate of long-term survival after surgery is, on the average *at best,* only ten or fifteen percent. And once the cancer has metastasized to a second location, surgery has almost *no* survival value whatsoever. The reason, of course, is that, like the other therapies approved by orthodox medicine, surgery removes only the tumor. It does not remove the cause.

The rationale behind X-ray therapy essentially is the same as with surgery. The medical objective is to remove the tumor, but to do so by burning it away rather than cutting it out. Here, also, it is primarily the non-cancer cell that is destroyed. The more malignant the tumor, the more resistant it is to radio therapy. This should be obvious for, if it were the other way around, then X-ray therapy would have a high degree of success—which, of course, it does not.

If the average tumor is composed of both cancer and non-cancer cells, and if radiation is more destructive to non-cancer cells than to cancer cells, then it would be logical to expect the results to be

a *reduction* of tumor *size,* but also an *increase* in the *percentage of malignancy.* This is, in fact, exactly what happens.

Commenting on this mechanism, Dr. John Richardson has explained it this way:

> Radiation and/or radiomimetic poisons *will* reduce palpable, gross or measurable tumefaction. Often this reduction may amount to seventy-five percent or more of the mass of the growth. These agents have a selective effect—radiation and poisons. They selectively kill everything except the definitively neoplastic [cancer] cells.
>
> For example, a benign uterine myoma will usually melt away under radiation like snow in the sun. If there be neoplastic cells in such tumor, these will remain. The size of the tumor may thus be decreased by ninety percent while the relative concentration of definitively neoplastic cells is therby increased by ninety percent.
>
> As all experienced clinicians know—or at least should know—after radiation or poisons have reduced the gross tumefaction of the lesion the patient's general well-being does not substantially improve. To the contrary, there is often an explosive or fulmination increase in the biological malignancy of his lesion. This is marked by the appearance of diffuse metastasis and a rapid deterioration in general vitality followed shortly by death. [5]

And so we see that X-ray therapy is cursed with the same limitations and drawbacks of surgery. But it also has one more: it actually increases the likelihood that cancer will develop in other parts of the body!

Yes, it is a well-established fact that excessive exposure to radioactivity is an effective way to induce cancer. This was first demonstrated by observing the increased cancer incidence among the survivors of Hiroshima, but it has been corroborated by many independent studies since then. For example, a recent headline in a national circulation newspaper tells us: FIND ALARMING NUMBER OF CANCER CASES IN PEOPLE WHO HAD X-RAY THERAPY 20 YEARS AGO. [6]

The *Textbook of Medical Surgical Nursing*, a standard reference volume for Registered Nurses, is most emphatic on this point. It says:

> This is an area of public health concern because it may involve large numbers of people who may be exposed to low levels of radiation over a long period of time. The classic example is of the women employed in the early 1920's to paint watch and clock dials with luminizing (radium-containing) paints. Years later, bone sarcomas resulted from the carcinogenic effect of the radium. Similarly, leukemia occurs more frequently in radiologists than other physicians. Another example is the Hiroshima survivors who have shown the effects of low levels of radiation. . .

Now to the question of statistics. Again we find that, on the average, there is little or no solid evidence that radiation actually improves the patient's chances for survival. The National Surgical Adjuvant Breast Project, previously mentioned in connection with surgery, also conducted studies on the effect of irradiation, and here is a summary of their findings:

> From the data available it would seem that the use of post-operative irradiation has provided no discernible advantage to patients so treated in terms of increasing the proportion who were free of disease for as long as five years. [7]

This is an embarrassingly difficult fact for a radiologist to face, for it means, quite literally, that there is little real justification for his existence in the medical fraternity. If he were to admit publicly what he knows privately from experience, a guy could talk himself right out of a job! Consequently, one does not expect to hear these facts being discussed by radiologists or those whose livelihood depends on the construction, sale, installation, use, or maintenance of the multi-million dollar linear accelerators. It comes as a pleasant surprise, therefore, to hear these truths spoken frankly and openly by three well known radiologists sharing the same platform at the same medical convention. They were William *Powers*, M.D., Director of the Division of Radiation Therapy at the Washington University School of Medicine, Philip *Rubin*, M.D., Chief of the Division of Radiotherapy at the University of Rochester Medical School, and Vera *Peters*, M.D., of the Princess Margaret Hospital in Toronto, Canada. Dr. Powers states:

> Although preoperative and postoperative radiation therapy have been used extensively and for decades, it is still not possible to prove unequivocal clinical benefit from this combined treatment . . . Even if the rate of cure does improve with a combination of radiation and therapy, it is necessary to establish the cost in increased morbidity which may occur in patients without favorable response to the additional therapy. [8]

Dr. Rubin's statement was even more to the point. After reviewing the statistics of survival previously published in the *Journal of the American Medical Association*, he concluded:

The clinical evidence and statistical data in numerous reviews are cited to illustrate that no increase in survival has been achieved by the addition of irradiation.

To which Dr. Peters added:

> In carcinoma of the breast, the mortality rate still parallels the incidence rate, thus proving that there has been no true improvement in the successful treatment of the disease over the past thirty years, even though there has been technical improvement in both surgery and radiotherapy during that time.

Or, putting it even more succinctly, Dr. Irwin H. Krakoff, of the Sloan-Kettering Institute for Cancer Research, says simply:

> We are concerned with a disease for which there is no really satisfactory treatment. [9]

In view of all this, it is exasperating to find spokesmen for orthodox medicine continually warning the public against using Laetrile on the grounds that, supposedly, that will prevent the cancer patient from benefiting from "proven" cures.

Battling as a lone warrior within the enemy stronghold, Dr. Dean Burk of the National Cancer Institute repeatedly has laid it on the line. In a letter to his boss, Dr. Frank Rauscher, he said:

> In spite of the foregoing evidence, . . . officials of the American Cancer Society and even of the National Cancer Institute, have continued to set forth to the public that about one in every four cancer cases is now "cured" or "controlled," but seldom if ever backed up with the requisite statistical or epidemiological support for such a statement to be scientifically meaningful, however effective for fund gathering. Such a statement is highly misleading, since it hides the fact that, with systemic or metastatic cancers, the actual rate of control in terms of the conventional five-year survival is scarcely more than one in twenty. . . [10]

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[1] Walshe, Walter H., *The Anatomy, Physiology, Pathology and Treatment of Cancer*, (Ticknor & Co., Boston, 1844).

[2] Ravdin, R.G., et al., "Results of Clinical Trial Concerning the Worth of Prophylactic Oophorectomy for Breast Carcinoma," *Surgery, Gynecology & Obstetrics*, 131:1055, Dec., 1970. Also see "Breast Cancer Excision Less with Selection," *Medical Tribune*, Oct. 6, 1971, p. 1.

[3] "A Report on Cancer," paper delivered to the ACS's 11th Annual Science Writers Conference, New Orleans, Mar. 7, 1969.

[4] See "Results of Treatment of Carcinoma of the Breast Based on Pathological Staging," by F.R.C. Johnstone, M.D., *California Medical Digest*, Aug., 1972, p. 839. Also, "Consultant's Comment," by George Crile, Jr., M.D. *Surgery Gynecology & Obstetrics*, 134.211, 1972, Also "Project aims at Better Lung Cancer Survival," *Medical Tribune*, Oct. 20, 1971. Also statement by Dr. Lewis A. Leone, Director of the Department of Oncology at Rhode Island Hospital in Providence, as quoted in "Cancer Controls Still Unsuccessful," L.A. Herald Examiner, June 6, 1972, p. C-12.

[5] Open letter to interested doctors, Nov., 1972.

[6] The National Enquirer, Oct. 7, 1973, p. 29.

[7] Fisher, B., et al., "Postoperative Radiotherapy in the Treatment of Breast Cancer; Results of the NSAPP Clinical Trial," *Annals of Surgery*, 172, No. 4, Oct. 1970.

[8] "Preoperative and Postoperative Radiation Therapy for Cancer," speech delivered to the Sixth National Cancer Conference, sponsored by the American Cancer Society and the National Cancer Institute, Denver, Colorado, Sept. 18-20, 1968.

[9] Speech delivered before the American Society of Clinical Oncology in 1968.

[10] Letter to Congressman Frey. op. cit.

With regard to the use of chemotherapy, the results are equally unsatisfactory. Dr. John Trelford of the Department of Obstetrics and Gynecology at Ohio State University Hospital has said:

> At the present time, chemotherapy of gynecological tumors does not appear to have increased life expectancy except in sporadic cases . . . The problem of blind chemotherapy means not only a loss of the effect of the drugs, but also a lowering of the patient's resistence to the cancer cells owing to the toxicity of these agents.[10]

Dr. Saul A. Rosenberg, Associate Professor of Medicine and Radiology at Stanford School of Medicine, said, with regard to cancer chemotherapy:

> Worthwhile palliation is achieved in many patients. However, there will be the inevitable relapse of the malignant lymphoma, and, either because of drug resistance or drug intolerance, the disease will recur, requiring modifications of the chemotherapy program and eventually failure to control the disease process.[11]

Dr. Charles Moertel of the Mayo Clinic had this to say on the subject of chemotherapy:

> Our most effective regimens are fraught with risks and side-effects and practical problems; and after this price is paid by all patients we have treated, only a small fraction are rewarded with a transient

[10] "A Discussion of the Results of Chemotherapy on Gynecological Cancer and the Host's Immune Response." Sixth National Cancer Conference proceedings.

[11] "The Indications for Chemotherapy in the Lymphomas," Sixth National Cancer Conference proceedings.

> period of usually incomplete tumor regression . . . Our accepted and transitional curative efforts, therefore, yield a failure rate of 85% . . . Some patients with gastrointestinal cancer can have very long survival with no treatment whatsoever. [12]

The FDA argues strenuously that trafficking in Laetrile carries with it the danger that people might be misled into subscribing to unsatisfactory cures. If the unsatisfactory results from state-sanctioned cancer remedies were actually known to the general public, it is not unreasonable to conclude that the feeling would be that the misleading has been in the other direction.

C. Laetrile is destined only for Informed, Consenting, Adult, Terminal Cancer Patients Acting Under the Direction of Competent Physicians, and is to be Administered by said Physicians to the said Patients, and to none Else.

The essence of FDA's argument is that it serves a valid State purpose for the State to proscribe trafficking in Laetrile, in that Laetrile has not yet received an approved new drug application, which means that its efficacy has not yet been adequately demonstrated according to legal standards. Therefore, since the possibility exists that Laetrile may not be effective, the state should protect the public therefrom, for the same reason that it protects citizens from all other drugs not yet proven to be effective.

It must be remembered, however, that Laetrile is not a non-prescription drug. No one contends that it should be placed in the over-the-counter category, where protection

[12] Speech made at the National Cancer Institute Clinical Auditorium, May 18, 1972.

to the public against ineffective drugs becomes particularly important. Laetrile is furnished on prescription and will be administered by a doctor who is acquainted with the patient, and the characteristics of his illness. The doctor has spent many years preparing himself for this responsibility, and has been certified by the State as a person qualified to prescribe and administer treatments according to his best judgment. In many cases, these doctors have had years of experience with Laetrile, and have seen its reaction on hundreds of terminal cancer patients. Under the circumstances it is difficult to conclude that a sufficiently substantial and compelling state interest is served—sufficient, in fact, to justify depriving the patient of his constitutional right of privacy—to take the choice of therapy away from the State's own licensed physician, and give it to a board, whose members have had no experience with Laetrile, and who know nothing about the patient. It must be remembers, moreover, that no question of toxicity is here presented. It has already been demonstrated in this brief that the State-approved alternatives are *very* toxic, in contrast to Laetrile, whose record is one of complete non-toxicity.

It must also be remembered that we are not concerned, here, with selling or promoting the sale of Laetrile to uninformed persons. There is no misrepresentation, no fraud, no snake-oil artistry, no quackery. The Laetrile-consumer is an adult, informed, consenting, cancer patient, acting under the direction and at the recommendation of his own personal physician. Where is the great State purpose which demands a disruption of this arrangement?

The California Court of Appeals, in the case of *People* v. *Privitera, supra* at page 781, said:

The doctor in California is licensed to practice only after meeting long rigid education, experience qualifications. He is bound by oath to preserve, to prolong, the life of his patient. He is under a legal duty, under threat of malpractice suit, to act in accordance with the generally accepted standards of medical practice in his community in this state. He is required under threat of malpractice to treat only after receiving the informed consent of the patient. (*Cobbs* v. *Grant,* supra, 8 Cal. 3d 229, 104 Cal. Reptr. 505, 502 p.2d 1.) These are the "rational means" society through law has imposed to insure a high standard of performance by the California doctor. It follows after such rigid standards are met, the matter of choice of treatment of the informed consenting patient becomes "a purely medical determination, which is within a doctor's professional judgment." (*Aden* v. *Younger*, supra, 57 Call. App. 3d 662, 677, 129 Cal. Rptr. 535, 545.)

> "Reliance must be placed upon the assurance given by his license, . . . that he possesses the requisite qualifications." (*Dent* v. *State* of *West Virginia,* 129 U.S. 114, 122-123, 9 S. Ct. 231, 233, 32 L. Ed. 623.)

Limiting this exercise of the doctor's professional judgment on some vague suspicion that "various persons" in this state are engaging in quackery does not follow as a matter of logic.

The premise that "various persons,"—conman, snake oil salesman,—have made or will make false and misleading representations to the public concerning the diagnosis, treatment and cure of cancer certainly warrants, as a rational means, the law which prohibits and makes criminal such acts. Health and Safety Code section 1714 accomplishes

this precise purpose. It prohibits a false representation with intent to defraud of any device or substance or treatment as an effective cure for cancer. Dr. Privitera does not contest the appropriateness of Health and Safety Code section 1714 as it does fit the announced legislative purpose.

D. There is no Rational Relationship between the alleged Compelling State Purpose of Discouraging Recourse to non-State-Approved Alternative Treatments, and the Means Employed to Accomplish this Purpose, viz., the Proscription Placed (1) on the Importation of Laetrile, or (2) on its Transportation in Interstate Commerce.

So much has been said in this brief on this point that little need here be added. If this case involved a situation where: 1) the state-prescribed treatments were clearly effective; 2) the state non-prescribed alternatives were clearly ineffective; 3) the patient was acting on his own, without knowledge, and without professional guidance; and 4) the proscription of Laetrile did actually succeed in discouraging cancer patients from having recourse to ineffective and unsanctioned remedies at the expense of effective state-sanctioned alternatives, then the FDA would have a strong case. The facts, however, are exactly the opposite of the above in each case. The state-prescribed treatments are of very limited effectiveness. There is very substantial evidence to indicate that the state non-prescribed alternative (Laetrile) is more effective than the state-prescribed treatment, at least in a great number of instances, in prolonging life. Its record, moreover, for reducing pain is excellent. The Laetrile patient is informed, and acts under the direction of a competent physician. Finally, the action of the FDA

has *not* cut down the use of Laetrile. All it has done is to force perhaps hundreds of thousands of patients to go to Mexico, or to Canada, or to Germany, or elsewhere, to submit to the latters' treatment at great cost to themselves. In almost every case, as has been previously pointed out, these patients have already submitted to state-sanctioned treatments, which have failed. That is why they have opted for Laetrile.

Moreover, the action of the FDA has had exactly the wrong effect: It has driven Laetrile underground; it has developed a black market for it and raised its prices; it has increased the patient's expenses at a time when he could least afford it; it has made lawbreakers out of honest citizens; it has taken much of the manufacture of Laetrile out from under the supervision of the FDA for purposes of ensuring good manufacturing practices, and purity of quality, and has thus encouraged inferior-quality production; and, finally, it has discouraged the sharing of information about it, and has made it extremely difficult to accomplish what everyone wants accomplished: namely, the obtaining of empirical confirmation of Laetrile's claims.

The Court cannot fail to find it of great interest that as of this date, nineteen states have already enacted legislation specifically approving and legalizing the administration of Laetrile to cancer patients by a licensed physician. All this has occurred within approximately the last three years. Many more states will probably add themselves to the nineteen. What will be the position of a terminal cancer patient then, who feels that he is dying because of his inability to procure Laetrile (because of the proscription on its interstate transportation), but who is residing in a state which sanctions it but cannot produce it (Alaska, for example)? What will happen if and

when a substantial portion of the states (or perhaps all of them) legalize Laetrile, and the FDA continues to proscribe its transportation in interstate commerce?

II.

LAETRILE IS NOT A NEW DRUG FOR THE REASONS (AMONG OTHERS) THAT IT IS EXEMPT BY VIRTUE OF THE PROVISIONS OF SECTION 107 OF PUB. L. 87-781.

Amicus adopts the argument of Judge Bohanon, *in toto*, on this point (Point IV, pp. 1294 through 1298 of his opinion).

III.

WHEN APPLICABLE TO AN INFORMED CONSENTING TERMINAL CANCER PATIENT, THE TESTS OF "SAFETY" AND "EFFECTIVENESS", AS PROVIDED BY SECTION 201(p)(1) OF THE ACT (21 U.S.C. 321(p)(1), HAVE NO MEANING IN THE ABSENCE OF SPECIAL STANDARDS APPLICABLE TO THOSE CIRCUMSTANCES.

Amicus adopts the arguments of Judge Seth, of the Tenth Circuit Court of Appeals, covering this point insofar as it applies to safety. In the absence of special standards, the test of "safety" cannot be rationally applied to terminal cancer patients. *Amicus* contends that terminal cancer patients are as entitled to "safe" drugs as any other patient, but that rational standards must be formulated according to which the test can be applied. However, in view of the fact that the District Court found from the record that Laetrile was generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as being safe, and thus meeting the requirements of the exemption provided in section 201(p)(1) of the Act, 23 U.S.C. 321(p)(1), since Laetrile is therefore not a new drug, the consideration of this point is moot.

CONCLUSION

Amicus does not challenge the right of the State to administer public health programs, and, through the exercise of its police power, to protect human life, even to the point of prohibiting self-destruction. The position of this brief, however, is that the exercise of such right and power must be subject to reasonable limitations, lest the absurdities created by an unreasonable application thereof result in violating the correlative right guaranteed to each individual to regulate his own life. The latter right is just as sacred as the right of the State to prevent him from destroying his life.

In the instant case, the arguments favoring the State's exercising its police power to withhold Laetrile from the plaintiff and those in his class, seem out of touch with reality. We are not dealing here with protecting an uninformed sick person from the blandishments of an unprincipled promoter of quack remedies. Rather we are dealing with a terminal cancer patient who has probably had little else on his mind for months—perhaps years. He has placed himself in the care of a physician, and has discussed the matter with him. The latter has recommended Laetrile—probably as a last resort, after all else has failed. The patient has been told that he stands a good chance of being relieved from his pain and suffering. He is told that although no one can promise him a "cure", or even a remission, the past record of Laetrile does show a number of recoveries by patients who had previously been characterized as hopeless.

If such a patient, knowing all the facts and risks, elects to take a course of action recommended to him by the physician in whom he has placed confidence, can it be said that such a decision is so egregiously irrational

that the State has a duty to intervene, and to forbid him to carry out his own desires?

The State's position would be more convincing if its proffered alternatives had a better record. The success record of these alternatives is notoriously poor. In view of this fact, no rational person could question the need to expand our knowledge of cancer on every front. Science should not fear to initiate new approaches where old ones have proven barren. To do this, however, a reasonable flexibility in administering the Act is imperative. An unrealistic and unnecessarily-rigid application of its restrictions will result in "locking in" all the present modalities, and locking out all the new, and competing ones. But this is the very result which society must repugn.

If society is ever to conquer the monster cancer, it will be by encouraging scientists to tread paths that have never been trodden before. *This will not be accomplished by imposing more fines, more prison sentences, more restrictions.* It will be accomplished by granting a reasonable flexibility to the law's administration, to the end that needed protection may be assured, on the one hand, and innovation encouraged, on the other. For this reason, *Amicus* asks this honorable Court to decree that the injunction issued by the trial court be made permanent.

Respectfully submitted,

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